UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,185	01/22/2007	Motoshi Shoda	2870-0265PUS2	5571

2292 7590 02/05/2008
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
CHUNG, SUSANNAH LEE

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
02/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,185	SHODA ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *65-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-53,55 and 58-64* is/are rejected.

7)☒ Claim(s) *53,54,56,57,67 and 68* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/06 and 1/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-68 are pending in the instant application. Claims 1-30 are canceled.

Priority

This application is a 371 of PCT/JP04/11952, filed on 08/13/2004.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. 2003-293590 filed in the Japanese Patent Office on 8/18/2003, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 2/13/06 and 1/31/07 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

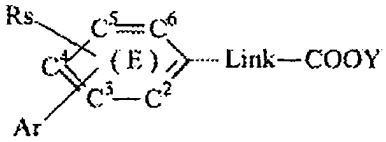
Response to Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 10/30/2007 is acknowledged. Specially, the election of species of the compound N-b-74 is acknowledged.

Scope of the Elected Invention

Claims 31-64 and 67-68 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows:

Compounds of formula (I), 

, depicted in claim 1, page 2, its medicaments and agents.

Scope of Withdrawn Subject Matter

Claims 65 and 66 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

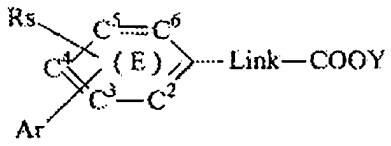
Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

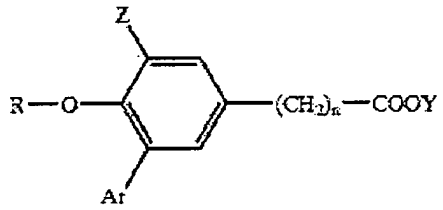
Claims 31-52, 55, and 58-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Num. 6,867,320 (`320 Patent).

Instant claims 31-52, 55, and 58-64 disclose compounds, medicaments and agents of formula (I), 

, wherein Rs is D-Rx, wherein D is oxygen and Rx is an alkyl group; Ar is a bicyclic moiety; Link is a hydrocarbon moiety; and Y is hydrogen or alkyl.

Determination of the scope and content of the prior art (MPEP § 2141.01)

`320 Patent teaches compounds, medicaments and agents of formula (I),



, wherein R is alkyl, Ar is a bicyclic moiety; Y is hydrogen or alkyl. Claims 1-19 of `320 Patent teach the compounds of the instant application, wherein D is oxygen. Claims 20 and 22-26 of `320 Patent teach the medicament comprising the compound of claims 1-19. Claim 21 of `320 Patent teaches the agent comprising the compound of claims 1-19 as the active ingredient.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between `320 Patent and the instantly claimed compounds is that `320 Patent claims where D is oxygen, while the instant claims are broader in scope and claim where

D also includes nitrogen, sulfur, carbonyl and a direct bond. Although the claims are not identical they are not patentably distinct from each other. The instant claims 31-52, 55, and 58-64 disclose wherein D is oxygen, which reads on the prior art.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

Although the conflicting claims are not identical, they are not patentably distinct from each other because the same compounds, medicaments and agents are taught in the `320 patent. The instant claims are broader in scope than the `320 Patent, but based on the teachings of the `320 Patent, the instantly claimed compounds, medicaments and agents, wherein D is oxygen would be obvious to one of ordinary skill in the art. The motivation to optimize the compounds of the `320 Patent is the expectation that they will have similar pharmacological use and properties.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons describe below.

As stated in MPEP 2164.01(a), "there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;
6. the amount of direction or guidance presented [by the inventor];
7. the presence or absence of working examples; and
8. the quantity of experimentation necessary [to make and/or use the invention].

The eight Wands factors are applied to Claims 62-64 of the present invention below:

(1) The Nature of the Invention

Claims 62-63 are directed to an agent that suppresses production of prostaglandin and or leukotriene using a compound according to claim 45 as an active ingredient.

Claim 64 is directed to an agent that can prevent or treat pulmonary fibrosis using a compound according to claim 31 as an active ingredient.

(2) The Breadth of the claims

Claims 62-64 will be give its broadest reasonable interpretation. The applicable rule for interpreting the claims is that "each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir.

1997). In view of this rule, the broad generic claims 31 and 45 will be interpreted to suppress production of prostaglandin or prevent/treat pulmonary fibrosis.

(3) The state of the prior art

It was known in the art at the time of this application that prostaglandins and various leukotrienes are metabolites of arachidonic acid and that they trigger various kinds of physiological reactions by mammals by binding to their respective receptors expressed on cell surfaces or express intracellulary.

In US Patent 6,867,320, it was shown that the compounds of formula (I), wherein D is oxygen have some pharmaceutical utility in inhibiting production of prostaglandin and/or leukotrienes. The extent of the inhibition is unknown and the disorders that can be treated with the compound were also unknown, except for a generic class of disorders such as inflammatory disorders. The use of the instantly claimed compounds in the complete suppression of prostaglandin and/or leukotriene or the prevention of pulmonary fibrosis is unknown.

(4) The relative skill of those in the art

The level of skill in the art (pharmaceutical chemists, physicians) would be high.

(5) The predictability or unpredictability of the art

It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement varies inversely with the degree of unpredictability in the factors involved. In re Fisher, 427 F.2d 833, 839. Therefore, the more unpredictable an area, the more specific enablement is needed in order to satisfy the statute. Added to the unpredictability of the art itself

is the question whether some activity against prostaglandin and leukotriene by one of the compounds of the present invention could be reliably and predictably extrapolated to in vitro and in vivo activity in patients to completely suppress prostaglandin and/or leukotriene. In addition, could the instantly claimed compounds be used to prevent pulmonary fibrosis in patients. There is no absolute predictability, even in view of the high level of skill in the art.

(6) The amount of direction or guidance presented (by the inventor)

The specification in the present invention discloses some biological data that the instantly claimed compounds show inhibitory activity against prostaglandin and leukotrienes, but fails to show how it completely suppresses it or how it prevents pulmonary fibrosis in a patient population. Even absent this data, if there was data that could be reasonably and reliably extrapolated to come to find this activity it would be sufficient, but the instant specification discloses more about the chemical synthesis of the compounds rather than the biological and pharmaceutical utility of the compounds.

(7) The presence or absence of working examples

As noted in the previous section, the specification fails to disclose working examples that show complete suppression or prevention of pulmonary fibrosis.

(8) The quantity of experimentation necessary (to make and/or use the invention)

Given the absence of direction or guidance (or working examples) in the specification for the role of the compounds of formula (I), it would cause a skilled artisan an undue amount of experimentation to practice this invention to determine which patients with which diseases would benefit from which of the many claimed compounds within the scope of the invention with a reasonable expectation of success.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

REBECCA ANDERSON
PRIMARY EXAMINER

SLC

Rebecca Anderson
Primary Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 30 January 2008